

NOV 16 2000

**stryker**  
LEIBINGER4100 East Milham Avenue  
Kalamazoo, MI 49001  
Phone (616) 323-7700  
(800) 253-7370**510(K) SUMMARY OF SAFETY AND EFFECTIVENESS:**

NewGen System

**General Information**

Proprietary Name:	NewGen System
Common Name:	Bone Plates Bone Fixation Fasteners
Classification Name(s):	Bone Plates Bone Fixation Fasteners
Classification Code(s):	76 JEY (21 CFR 872.4760) Bone Plates 87HWC (21 CFR 888.3040) Bone Fixation Fasteners
Submitter:	Stryker Leibinger 4100 East Milham Avenue Kalamazoo, MI 49001 800-253-7370
Submitter's Registration #:	1811755
Manufacturer's Registration #:	8010177
Contact Person:	Robin L. Rowe Regulatory Affairs Associate Phone: 616-323-7700 x3295 Fax: 616-324-5412
Summary Preparation Date:	August 21, 2000

**Device Description**

The Stryker Leibinger NewGen system is a two-module system for the stabilization and fixation of mandible fractures and mandibular reconstruction surgical procedures. Included will be the 2.0mm and 2.3mm Fracture/Reconstruction Module. The 2.0 and 2.3mm Fracture/Reconstruction Modules will consist of straight, angled, curved plates for fractures and hemi/full mandible bridging plates for reconstruction. The screws in the modules include 2.0-3.0mm self-tapping, normal, compression and locking screws that will vary from 4mm-42mm in length.

## **Intended Use**

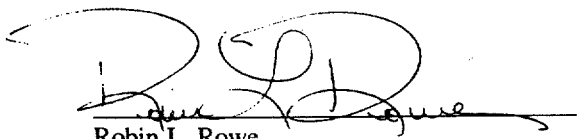
The Stryker Leibinger NewGen System is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fractures and mandibular reconstruction.

## **Substantial Equivalence**

### **EQUIVALENT PRODUCTS:**

The Leibinger® NewGen System is substantially equivalent to several legally marketed devices in commercial distribution. Examples of these devices is listed below and additional literature is included in Appendix C.

1. Wurzburg® Titanium Mini Bone Plates and Screws-WLorenz® K854886
2. Steinhauser® Titanium Mini Bone Plates and Screws-WLorenz® K862482
3. Synthes® 2.0 MM Locking Plate System (2.0 LPS)- Synthes® K974555
4. Synthes® Locking Reconstruction Plate (LRP) with Condylar Head- Synthes® K990637
5. KLS Martin® Mandibular Fracture/Reconstruction System-KLS Martin K950045
6. Synthes® Mandibular Modular fixation System- Synthes K954385
7. Lorenz® Titanium Fracture/Reconstruction Plating- WLorenz® K001238
8. Lorenz® Reconstruction system with Modular Screw- WLorenz® K980512



Robin L. Rowe  
Regulatory Affairs Associate  
August 21, 2000



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV 16 2000

Ms. Robin L. Rowe  
Regulatory Affairs Associate  
Stryker Instruments  
4100 East Milham Avenue  
Kalamazoo, Michigan 49001

Re: K002619  
Trade Name: Newgen System  
Regulatory Class: II  
Product Code: JEY  
Dated: August 16, 2000  
Received: August 23, 2000

Dear Ms. Rowe:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

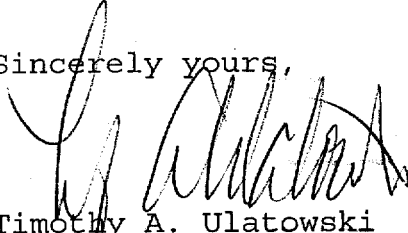
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski  
Director

Division of Dental, Infection Control  
and general Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known): \_\_\_\_\_

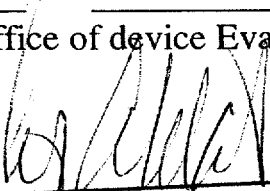
Device Name: NewGen System

Indication For Use:

The Stryker Leibinger NewGen System is a mandibular plate and screw system intended for stabilization and rigid fixation of mandibular fractures and reconstruction.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

\_\_\_\_\_  
Concurrence of CDRH, Office of device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number

K002619

Prescription Use \_\_\_\_\_ or Over-The-Counter Use \_\_\_\_\_  
(per 21 CFR 801.109)

(Optional Format 1-2-96)